DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

g415934

MAR 25 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. George MacDonald
President
Anti Aging Solutions Inc.
1 Westside Drive, Unit 5
Toronto, Ontario, M9C 1B2
Canada

Dear Mr. MacDonald:

We are writing to you because on December 31, 2003, the Buffalo District Office, Food and Drug Administration (FDA), detained a shipment that revealed a serious regulatory problem involving the Revitalite Beautifying Soft Light Laser(Revitalite), which is marketed by your firm. We understand that this product is manufactured for your company by [redacted] Furthermore, we understand that while your company has submitted a section 510(k) premarket notification for the Revitalite (K033765), the FDA has not yet cleared the product for sale in the United States (U.S.).

Under section 201(h) of the Food, Drug and Cosmetic Act (the Act), an instrument is considered a medical device if it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of diseases, or because it is intended to affect the structure or any function of the body. According to the information you submitted with your section 510(k) premarket notification, the Revitalite is a low level laser intended for the treatment of chronic neck and shoulder pain of musculoskeletal origin. The Revitalite is therefore a medical device within the meaning of section 201(h) of the Act.

The Act requires that manufacturers of medical devices obtain marketing clearance or approval for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records show that you did not obtain marketing clearance or approval before you began offering the Revitalite for sale. Because you do not have marketing clearance or approval from

the FDA, marketing your product in the U.S. is a violation of the law. Specifically, the product is adulterated under section 501(f)(1)(B) of the Act and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you have not received clearance on a section 510(k) premarket notification that shows your device is substantially equivalent to other devices that are legally marketed. Your product is adulterated under the Act because the law requires, and you do not have, an approved premarket approval (PMA) application that shows your device is safe and effective. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the Agency. 21 CFR 807.81(b).

You should know that this serious violation of the law may result in the FDA taking regulatory action against you without further notice. These actions include, but are not limited to, detaining without physical examination upon entry into the U.S. all Revitalite devices marketed by your firm. Also, federal agencies in the U.S. are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding U.S. government contracts.

It is necessary to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Ms. Cory Tylka, Consumer Safety Officer, Electronic Products Branch, Division of Enforcement B, Office of Compliance (HFZ-342), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850 USA.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance or approval for the Revitalite and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers and marketers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Cory Tylka of my staff at 1-301-594-4654, ext. 154 or email: cst@cdrh.fda.gov.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health